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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,984	02/15/2001	William John Coates	P31957	4229

20462 7590 04/29/2005

SMITHKLINE BEECHAM CORPORATION
CORPORATE INTELLECTUAL PROPERTY-US, UW2220
P. O. BOX 1539
KING OF PRUSSIA, PA 19406-0939

EXAMINER

COPPINS, JANET L

ART UNIT PAPER NUMBER

1626

DATE MAILED: 04/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/600,984	Applicant(s) COATES ET AL.	
	Examiner Janet L. Coppins	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-34 is/are pending in the application.
- 4a) Of the above claim(s) 29-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18, 19, 28 and 32-34 is/are rejected.
- 7) ☒ Claim(s) 17 and 20-27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| <p>1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6) <input type="checkbox"/> Other: _____</p> |
|---|---|

JK

DETAILED ACTION

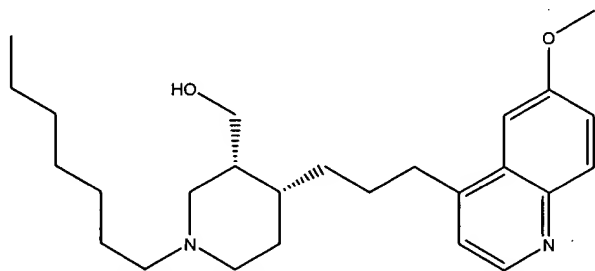
Claims 17-34 pending in the instant application.

Information Disclosure Statement

1. Applicant's Informational Disclosure Statement, filed July 25, 2000, has been considered by the Examiner. Please refer to the Applicant's copy of the PTO-1449 form submitted herewith.

Election/Restrictions

2. Applicants' election **with traverse** of Group I, claims 17 and 20-27, drawn to methods of using compounds according to Formula (I), in the response filed January 31, 2005, is acknowledged. A further election of the compound of Example 87, found on page 66 of the specification:



[3R,4R]-1-heptyl-3-hydroxymethyl-4-[3-(6-methoxyquinolin-4-yl)propyl]piperidine

is also acknowledged.

3. Applicants' traverse that Restriction under PCT Rules 13.1 and 13.2 of the instant claims is improper, and that the compounds of the instant invention differ from the compounds of the '106 patent by the presence of certain substituents on the quinoline ring. Applicants also contend that, "...the claims of the present invention are linked to form a single general inventive concept, i.e. where compounds of Formula (I) of the present invention possess a common structural compound core with specific substituent groups fixed in specific positions and/or which are

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limited in number position and type as distinguished from prior art..." on page 4 of Applicants' response.

Applicants' arguments have been considered but have not been found persuasive. A significant structural element that is shared by all of the alternatives is not present in the compounds of Formula (I). In the Office Action dated November 29, 2004, the Examiner indicated what was considered the special technical feature, i.e. the same structure as drawn on page 8 of the Restriction Requirement, and Applicants are reminded that variables are **excluded**. At the most, the special technical feature might contain an alkyl moiety off of the piperidine ring. However, variables are *not* considered when ascertaining the special technical feature. Since the all of the R moieties as well as A, B, n, and m are variables, these aspects were not considered part of the special technical feature. Additionally, in reviewing the "Examples Concerning Unity of Invention" this further supports the Examiner's position. In Example 19, the iminothioether group ($-N=C-SCH_3$) attached to a six membered ring was indicated as the significant structural element. It further states that a six membered heterocyclic ring would not have been of sufficient similarity to allow a Markush grouping exhibiting unity. Therefore, the unity of invention is still considered to be lacking between compounds according to formula I, as well as methods of use claims.

Furthermore, as stated previously, the substituents vary extensively and when taken as a whole result in vastly different compounds. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper. Additionally, the vastness of the claimed subject matter and the

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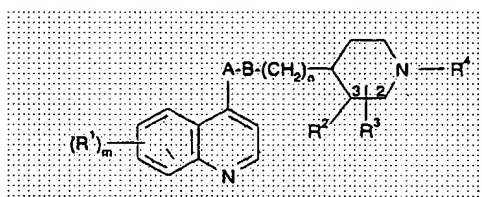
complications in understanding the claimed subject matter imposes a burden on any examination of the claimed subject matter.

4. The requirement is still deemed proper and is therefore made FINAL. Claims 29-31, and 17-28 **in part** withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions, there being no allowable generic or linking claim.

Status of the Claims

5. Claims 17-34 pending in this application. Claims 29-31, drawn to processes of preparation, are currently withdrawn from consideration by the Examiner. The scope of the invention of the elected subject matter is as follows:

Compounds according to Formula (I), with the core structure:



wherein: A is CR^6R^7 , B is CR^8R^9 , and the remaining variables are as defined.

As a result of the election and the corresponding scope of the invention identified above, the remaining subject matter of claims 17 and 20-27 **withdrawn** from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to non-elected inventions (i.e. methods of using compounds according to Formula I that are excluded from the scope of the invention defined above, when A is NR^{11} , O, or $S(O)_x$ and B is NR^{11} , O, or $S(O)_x$). The withdrawn compounds contain varying functional groups for the A and B moieties including alkoxy, amino, sulfonyl, sulfanyl, sulfonamide, carboxamide, nitro, etc. which are chemically recognized to differ in structure and function. Therefore the subject matter that has been withdrawn from consideration

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as being non-elected subject matter, differs materially in structure and composition and has been restricted properly, and a reference that anticipates the elected subject matter would not render obvious the withdrawn subject matter, and the fields of search would not be coextensive.

Rejoinder

6. In view of a fair interpretation of the claims, the Examiner will rejoin compound and composition claims 18, 19, 28, and 32-34 that are commensurate in scope with the methods of use compounds of claims 17 and 20-27 (i.e. compounds according to Formula I wherein A is NR^{11} , O, or S(O)_x and B is NR^{11} , O, or S(O)_x), which is **Group VI** of the Restriction Requirement of November 29, 2004.

7. Applicant is reminded that upon the cancellation of subject matter to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 17-28 and 32-34 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 52 of copending Application No. 2003203917. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows:

Applicants are claiming quinoline derivatives according to Formula (I) and the above-identified examined invention (as described in paragraphs 5-6) that are useful for treating bacterial infections in mammals.

Erskine et al teach compositions containing quinoline derivatives having the same core structure (Ib) and falling into the same definition of the invention, please see part B of claim 52. The compounds disclosed in the Erskine et al patent publication fully encompass the compounds of the instant invention, in claims 18, 19, 28, and composition claims 32-24. Minus a showing

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of unobvious results, it would have been obvious to one of skill in the art to prepare the quinoline compounds as instantly claimed in claims 18, 19, 28, and 32-34 since the Erskine publication discloses the same genus of compounds as instantly recited.

Claim Objections

11. Claims 17-28 objected to for containing non-elected subject matter.

12. Claim 34 objected to under 37 CFR 1.75 as being a substantial duplicate of claim 32.

When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Conclusion

13. In conclusion, claims 17-34 are pending, however claims 29-31 and 17-28 in part are withdrawn from consideration as directed to non-elected subject matter. Claims 18, 19, 28, and 32-24 are currently rejected.

Telephone Inquiry

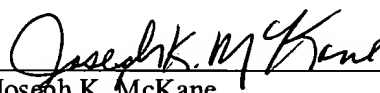
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Coppins whose telephone number is 571.272.0680. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Joseph K. McKane can be reached on 571.272.0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Coppins
April 25, 2005



Joseph K. McKane,
SPE, Art Unit 1626